permanent and may be removed by your dentist.''

(f) *Optional additional labeling statements*—(1) *For fluoride treatment rinses and preventive treatment gels.* The following labeling statement may appear in the required boxed area designated ''APPROVED USES'': ''The combined daily use of a fluoride preventive treatment'' (select one of the following: ''rinse'' or ''gel'') ''and a fluoride toothpaste can help reduce the incidence of dental cavities.''

(2) *For dentifrice products containing 1,500 ppm theoretical total fluorine.* ''Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities.''

[60 FR 52507, Oct. 6, 1995; 60 FR 57927, Nov. 24, 1995; 61 FR 51187, Oct. 7, 1996; 64 FR 13296, Mar. 17, 1999]

§ 355.55 Principal display panel of all fluoride rinse drug products.

In addition to the statement of identity required in § 355.50, the following statement shall be prominently placed on the principal display panel: ''IMPORTANT: Read directions for proper use.''

§ 355.60 Professional labeling.

(a) The labeling for anticaries fluoride treatment rinses identified in § 355.10(a)(3) and (c)(3) that are specially formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) may contain the following additional dosage information: Children 3 to under 14 years of age: As a supplement in areas where the water supply is nonfluoridated (less than 0.3 parts per million (ppm)), clean the teeth with a toothpaste and rinse with 5 milliliters (mL) of 0.02 percent or 10 mL of 0.01 percent fluoride ion rinse daily, then swallow. When the water supply contains 0.3 to 0.7 ppm fluoride ion, reduce the dose to 2.5 mL of 0.02 percent or 5 mL of 0.01 percent fluoride ion rinse daily.

(b) The labeling for products marketed to health to health professionals in package sizes larger than those specified in § 355.20 shall include the statements: ''For Professional Office Use Only'' and ''This product is not intended for home or unsupervised consumer use.''

Subpart D—Testing Procedures

§ 355.70 Testing procedures for fluoride dentifrice drug products.

(a) A fluoride dentifrice drug product shall meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake. The testing procedures for these biological tests are labeled *Biological Testing Procedures for Fluoride Dentifrices*; these testing procedures are on file under Docket No. 80N–0042 in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and are available on request to that office.

(b) The United States Pharmacopeia fluoride dentifrice reference standards along with reference standard stability profiles (total fluoride, available fluoride ion, pH, and specific gravity) required to be used in the biological tests are available to any purchaser upon written request to the United States Pharmacopeial Convention, Inc., 1260 Twinbrook Parkway, Rockville, MD 20852.

(c) Alternative testing procedures may be used. Any proposed modification or alternative testing procedures shall be submitted as a petition in accord with § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative testing procedure provides results of equivalent accuracy. All information submitted will be subjected to the disclosure rules in part 20 of this chapter.

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—Anthelmintic Drug Products

Sec.

Subpart C—Cholecystokinetic Drug Products

Subparts D–H [Reserved]

Subpart I—Deodorant Drug Products for Internal Use

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

Subpart A [Reserved]

Subpart B—Anthelmintic Drug Products

SOURCE: 51 FR 27759, Aug. 1, 1986, unless otherwise noted.

§ 357.101 Scope.

(a) An over-the-counter anthelmintic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 357.103 Definition.

As used in this subpart:

Anthelmintic. An agent that is destructive to worms.

§ 357.110 Anthelmintic active ingredient.

The active ingredient of the product is pyrantel pamoate when used within the dosage limits established in § 357.150(d)(1).

§ 357.150 Labeling of anthelmintic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''pinworm treatment.''

(b) *Indication.* The labeling of the product states, under the heading ''Indication,'' the following: ''For the treatment of pinworms.'' Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''Abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these conditions persist consult a doctor.''

(2) ''If you are pregnant or have liver disease, do not take this product unless directed by a doctor.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) Adults, children 12 years of age and over, and children 2 years to under 12 years of age: Oral dosage is a single dose of 5 milligrams of pyrantel base per pound, or 11 milligrams per kilogram, of body weight not to exceed 1 gram. Dosing information should be converted to easily understood directions for the consumer using the following dosage schedule:

Weight	Dosage (taken as a single dose) [1]
Less than 25 pounds or under 2 years old.	Do not use unless directed by a doctor.
25 to 37 pounds	125 milligrams.
38 to 62 pounds	250 milligrams.
63 to 87 pounds	375 milligrams.
88 to 112 pounds	500 milligrams.
113 to 137 pounds	625 milligrams.
138 to 162 pounds	750 milligrams.

Weight	Dosage (taken as a single dose) [1]
163 to 187 pounds	875 milligrams.
188 pounds and over	1,000 milligrams.

[1] Depending on the product, the label should state the quantity of drug as a liquid measurement (e.g., teaspoonsful) or as the number of dosage units (e.g., tablets) to be taken for the varying body weights. (If appropriate, it is recommended that a measuring cup graduated by body weight and/or liquid measurement be provided with the product.) Manufacturers should present this information as appropriate for their product and may vary the format of this chart as necessary.

(2) ''Read package insert carefully before taking this medication. Take only according to directions and do not exceed the recommended dosage unless directed by a doctor. Medication should only be taken on time as a single dose; do not repeat treatment unless directed by a doctor. When one individual in a household has pinworms, the entire household should be treated unless otherwise advised. See Warnings. If any worms other than pinworms are present before or after treatment, consult a doctor. If any symptoms or pinworms are still present after treatment, consult a doctor.

(3) ''This product can be taken any time of day, with or without meals. It may be taken alone or with milk or fruit juice. Use of a laxative is not necessary prior to, during, or after medication.''

(e) *Optional wording*. The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[51 FR 27759, Aug. 1, 1986; 52 FR 7831, Mar. 13, 1987, as amended at 53 FR 35810, Sept. 15, 1988]

§ 357.152 Package inserts for anthelmintic drug products.

The labeling of the product contains a consumer package insert which includes the following information:

(a) A discussion of the symptoms suggestive of pinworm infestation, including a statement that pinworms must be visually identified before taking this medication.

(b) A detailed description of how to find and identify the pinworm.

(c) A commentary on the life cycle of the pinworm.

(d) A commentary on the ways in which pinworms may be spread from person to person and hygienic procedures to follow to avoid such spreading.

(e) The appropriate labeling information contained in § 357.150

(Collection of information requirement approved by the Office of Management and Budget under control number 0910–0232)

[51 FR 27759, Aug. 1, 1986, as amended at 52 FR 2515, Jan 23, 1987]

§ 357.180 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain an additional indication: ''For the treatment of common roundworm infestation.''

Subpart C—Cholecystokinetic Drug Products

§ 357.201 Scope.

(a) An over-the-counter cholecystokinetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart in addition to each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[48 FR 27005, June 10, 1983]

§ 357.203 Definition.

As used in this subpart:

Cholecystokinetic drug product. A drug product that causes contraction of the gallbladder and is used during the course of diagnostic gallbladder studies (cholecystography).

[48 FR 27005, June 10, 1983]

§ 357.210 Cholecystokinetic active ingredients.

The active ingredient of the product consists of any of the following when used within the specified concentration and dosage form established for each ingredient:

(a) 50-percent aqueous emulsion of corn oil.

(b) Hydrogenated soybean oil in a suitable, water-dispersible powder. The hydrogenated soybean oil is food-grade, partially hydrogenated with a melting

point of 41 to 43.5 °C, an iodine value of 65 to 69, and a fatty acid composition as follows:

Fatty acid	Percent composition
Myristic acid	0.1
Palmitic acid	10.0
Palmitoleic acid	0.1
Stearic acid	13.5
Oleic acid	72.0
Linoleic acid	3.8
Linolenic acid	0.1
Arachidic acid	0.5
Behenic acid	0.2

[54 FR 8321, Feb. 28, 1989]

§ 357.250 Labeling of cholecystokinetic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''gallbladder diagnostic agent.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following: ''For the contraction of the gallbladder during diagnostic gallbladder studies.'' Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* [Reserved]

(d) *Directions.* The labeling of the product contains the following statements under the heading ''Directions'':

(1) ''Take only when instructed by a doctor:''

(2) *For products containing 50-percent aqueous emulsion of corn oil.*

(i) ''Shake well before using.''

(ii) Oral dosage is 60 milliliters 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(3) *For products containing hydrogeneated soybean oil.* Oral dosage is 12.4 grams in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[48 FR 27005, June 10, 1983, as amended at 51 FR 16267, May 1, 1986; 52 FR 7830, Mar. 13, 1987; 54 FR 8321, Feb. 28, 1989]

§ 357.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in § 357.210: *Indication.* ''For visualization of biliary ducts during cholecystography.''

[54 FR 8321, Feb. 28, 1989]

Subparts D–H [Reserved]

Subpart I—Deodorant Drug Products for Internal Use

SOURCE: 55 FR 19865, May 11, 1990, unless otherwise noted.

§ 357.801 Scope.

(a) An over-the-counter deodorant drug product for internal use in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 357.803 Definitions.

As used in this subpart:

(a) *Colostomy.* An external operative opening of the colon.

(b) *Deodorant for internal use.* An ingredient taken internally to reduce odors arising from conditions such as colostomies, ileostomies, or fecal incontinence.

(c) *Ileostomy.* An external operative opening from the ileum.

(d) *Incontinence.* An inability to retain urine or feces.

§ 357.810 Active ingredients for deodorant drug products for internal use.

The active ingredient of the product consists of either of the following when used within the dosage limits established for each ingredient in § 357.850(d):

(a) Bismuth subgallate.

(b) Chlorophyllin copper complex.

§ 357.850 Labeling of deodorant drug products for internal use.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''deodorant for internal use'' or as a ''colostomy or ileostomy deodorant.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in paragraph (b) of this section as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing bismuth subgallate identified in § 357.810(a).* ''An aid to reduce odor from a colostomy or ileostomy.''

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* (i) ''An aid to reduce odor from a colostomy or ileostomy.''

(ii) ''An aid to reduce fecal odor due to incontinence.''

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'': (1) *For products containing chlorophyllin copper complex identified in § 357.810(b).* (i) ''If cramps or diarrhea occurs, reduce the dosage. If symptoms persist, consult your doctor.''

(ii) The warning required by § 330.1(g) of this chapter concerning overdose is not required on products containing chlorophyllin copper complex identified in § 357.810(b).

(2) [Reserved]

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions.''

(1) *For products containing bismuth subgallate identified in § 357.810(a).* Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take up to an additional 100 milligrams daily in divided doses as required. The smallest effective dose should be used. Do not exceed 300 milligrams daily. Children under 12 years of age: consult a doctor.

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—Wart Remover Drug Products

Sec.

Subparts C–E [Reserved]

Subpart F—Corn and Callus Remover Drug Products

Subpart G—Pediculicide Drug Products